

REMARKS

1. In response to the Office Action mailed July 25, 2007, Applicants respectfully request reconsideration. Claims 1-38 were last presented in the application. Claims 22-31, 35-37 have been withdrawn. In the outstanding Office Action, all claims have been rejected. By the foregoing Amendments, claims 1-38 have been cancelled and claims 39-73 have been added. Thus, upon entry of this paper, claims 39-73 will be pending in this application. Of these 35 claims, 3 claims (claims 39, 55, and 70) are independent.

2. Based on the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Art of Record

3. Applicants acknowledge receipt of form PTO-892 listing additional references identified by the Examiner.

4. Applicants thank the Examiner for returning form PTO-1449 filed by Applicants on September 2, 2004, which has been initialed by the Examiner indicating that the Examiner has considered the references cited therein.

Drawings

5. Applicants thank the Examiner for indicating that the drawings filed on September 2, 2004 have been accepted for publication.

Election/Restrictions

6. Applicants thank the Examiner for acknowledging Applicants' election of Group I, claims 1-21, 32-34 and 38. Applicants have now cancelled the previously withdrawn non-elected claims. Applicants submit that new claims 39-73 are entirely consistent with the subject matter of previously elected Group I.

Specification

7. The Examiner has objected to the specification because the title of the invention is not descriptive. Applicants have amended the title of the invention to be "A Cochlear

Implant Having a Repositionable Implantable Housing.” Applicants respectfully submit that this new title is indicative of the invention to which the claims are directed and respectfully request that this objection be withdrawn.

8. The Examiner has further objected to the specification because page 20, line 28 refers to Figure 3-d, but mentions reference numbers only found in Figure 3-c. The Examiner suggested replacing the reference to Figure 3-d with a reference to Figure 3-c. Applicants have taken the Examiner’s suggestion and have replaced “FIGS. 3-d” with “FIG. 3-c.” As such, Applicants respectfully request that the above objection be withdrawn.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

9. The Examiner has rejected claims 32-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner states that the phrase “without there being any significant or indeed no change in the operation of the component” is indefinite because it is unclear whether any change in the operation is acceptable. By the foregoing Amendments, Applicants have cancelled claims 32-34. As such, Applicants submit that the claim rejections under 35 U.S.C. 112 have been rendered moot.

Claim Rejections under 35 U.S.C. § 102

10. Claims 1, 4-5, 10-14, 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,272,382 to Faltys *et al.*, (hereinafter, “Faltys 382”). Applicants have cancelled claims 1, 4-5, 10-14, 16 and 18-19 thereby rendering this rejection moot.

11. Claims 2, 3 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,308,101 to Faltys *et al.*, (hereinafter, “Faltys 101”). Applicants have cancelled claims 2, 3 and 38 thereby rendering this rejection moot.

Claim Rejections under 35 U.S.C. § 103

12. Claims 9, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys 382 in view of U.S. Patent No. 6,648,914 to Berrang *et al.*, (hereinafter, "Berrang"). Also, claims 6-8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys 382 in view of U.S. Patent No. 6,205,360 to Carter *et al.*, (hereinafter, "Carter"). Similarly, claim 21 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys 382 in view of Berrang in further view of U.S. Patent No. 6,161,046 to Maniglia *et al.*, (hereinafter, "Maniglia"). Furthermore, claims 32-34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys 382 in view of Faltys 101. Applicants have cancelled claims 6-8, 9, 15, 20-21 and 32-34 thereby rendering these rejections moot.

New Claims 39-73

13. Applicants have added new claims 39-73 and respectfully submit that no reference of record, taken alone or in combination, anticipates or renders obvious these new claims.

14. Faltys 382 is directed to a fully implantable cochlear implant that uses "at least three main modules... [that] include: (1) a small implantable cochlear stimulator (ICS) module, with permanently attached cochlear electrode array; (2) an implanted speech processor (ISP) module... and (3) an external module." (See, Faltys 382, col. 2, lines 50-60.) The ICS module includes the "same basic cochlear-stimulation circuitry used in implantable cochlear stimulator" and is connected to the ISP via a pigtail-lead. (See, Faltys 382, col. 2, line 63- col. 3, line 11.) The ISP is preferably in the shape of a rounded disk and includes a groove around or along the perimeter edge to provide a location where the pigtail lead may be coiled or wrapped. (See, Faltys 382, col. 3, lines 14-32.)

15. During the implantation of the fully implantable cochlear implant of Faltys 382, the ICS module is first implanted in a patient in a conventional manner. (See, Faltys 382, col. 3, lines 57-65.) This step requires the surgeon to insert the electrode array into the cochlear and secure the ICS within the recipient adjacent to the cochlear. (See, Faltys 382, col. 3, lines 57-65.) As would be appreciated by one of ordinary skill in the art, because the electrode array and the ICS of Faltys '382 are "permanently attached," the ICS is secured not only to prevent the ICS from moving, but also to secure the electrode array in a

desired position within the cochlear of the patient. Following implantation of the ICS, the ISP is implanted “adjacent to the ICS module, with the pigtail lead being wound around and contained within the edge channel groove of the ISP module.” (See, Faltys 382, col. 3, lines 60-66.)

16. In Faltys 382, when it becomes necessary or desirable to replace the ISP module, the ISP may be removed from the patient by rotating it to unwind the pigtail lead “much like a yo-yo.” (See, Faltys 382, col. 4, lines 5-15.) Once removed from the body, a new ISP is connected to the pigtail lead and inserted into the patient by rotating the new ISP to wind the pigtail lead back into the channel groove. (See, Faltys 382, col. 4, lines 15-23.) The main advantage of the system of Faltys 382 is that the ISP may be removed from the patient without disturbing the placement of the ICS. In other embodiments, the ISP of Faltys 382 communicates with the ICS via a radio frequency link to more easily achieve removability of the ISP without disturbing the position of the ICS. (See, Faltys 382, col. 4, lines 24-34.) **However, in all embodiments of Faltys 382, it is essential that the ICS remains in a stationary position because movement of the ICS “permanently attached” to the electrode array would result in an undesirable movement of the electrode array.** (See, Faltys 382, col. 11, lines 11-65.) As would be appreciated by one of ordinary skill in the art, movement of the electrode array while in the cochlea could potentially damage the cochlea.

Claim 39

17. Applicants respectfully assert that Faltys 382 fails to teach or suggest all elements of Applicants’ claim 39. Specifically, Faltys 382 completely fails to teach or suggest a “housing having therein electronics configured to output one or more stimulation signals...
... *wherein following implantation of at least a portion of said second region into the cochlea, said housing is rotatable about an axis of said housing*” as recited in part in claim 39. (Emphasis added.) As noted above, in embodiments of Faltys 382, the speech processing unit (ISP) may be removed from the recipient, while the implanted stimulator unit (ICS) remains in a fixed position. (See, Faltys 382, col. 4, lines 5-34.) Also as noted above, it is clear from Faltys 382 that the ICS must remain in a fixed position so as to prevent movement of the electrode array within the cochlea because the ICS is “permanently attached” to the electrode array. (See, Faltys 382, col. 2, lines 50-60.)

Therefore, because Faltys 382 discloses a device that utilizes an ICS unit that is retained in a fixed position to prevent movement of a “permanently attached” electrode array, Applicants assert that it would be unreasonable to assert that Faltys 382 teaches or suggests an implantable “housing having therein electronics configured to output one or more stimulation signals” that “is rotatable about an axis of said housing,” as recited in part in claim 39.

18. Even if one were to incorrectly find that the ICS of Faltys 382 was “rotatable about an axis of said housing,” such a device would still fail to teach or suggest all elements of Applicants’ claim 39. In particular, such a device would still fail to teach or suggest an implantable “housing having therein electronics configured to output one or more stimulation signals... wherein said housing and said first region are configured such that following implantation of said second region into the cochlea, said housing is rotatable about an axis of said housing... such that *said second region implanted in the cochlea remains substantially stationary during said rotation*” as recited, in part, in claim 39. (Emphasis added.) As explained in detail above, the ICS device of Faltys 382 is “permanently attached” to the electrode array. (See, Faltys 382, col. 2, lines 50-60.) This permanent attachment necessarily results in movement of the electrode array in response to movement of the ICS device. (See, Faltys 382, col. 11, lines 11-65.) As such, due to this permanent attachment and resulting movement, Applicants assert that it would be physically impossible to rotate the ICS of Faltys 382 about an axis while allowing any part of the electrode array implanted in the cochlea to remain substantially stationary. Therefore, because the ICS of Faltys 382 cannot be moved, let alone rotated, without causing movement of the electrode array, Applicants assert that it would be unreasonable to find that the device of Faltys 382 teaches or suggests a “housing having therein electronics configured to output one or more stimulation signals... wherein said housing and said first region are configured such that following implantation of said second region into the cochlea, said housing is rotatable about an axis of said housing... such that said second region implanted in the cochlea remains substantially stationary during said rotation” as recited in part in claim 39.

19. Applicants further assert that the other art of record, taken alone or in combination, fail to teach or suggest that which is missing from claim 39. In particular, Faltys 101,

which is in the same application family as Faltys 382 and discloses similar subject matter, fails to teach those elements that are lacking from Faltys 382.

20. Faltys 101 is directed to a fully implantable cochlear implant with an implanted rechargeable power source. (See, Faltys 101, col. 6, lines 27-42.) The cochlear implant of Faltys 101 uses a “wired” system with two or more implantable units. (See, Faltys 101, col. 9, lines 6-31.) One unit houses the speech processor and ICS, while the other houses the rechargeable power source. (See, Faltys 101, col. 9, lines 6-31.) Similar to Faltys 382, Faltys 101 completely fails to disclose that the unit containing the stimulator circuitry (the ICS) may be removed or repositioned. In fact, for the same reasons as discussed above with reference to Faltys 382, it is clear from the disclosure that, in Faltys 101, the unit containing the ICS must remain stationary because movement of the ICS would result in an undesirable movement of the permanently attached electrode array. (See, Faltys 382, col. 11, lines 1-55.)

21. For at least these reasons, Applicants assert that new claim 39 is patentable over the art of record. Therefore, Applicants respectfully assert that claim 39 is in condition for allowance.

Claim 55

22. Applicants respectfully assert that Faltys 382 fails to teach or suggest all elements of Applicants’ claim 55. Specifically, for the reasons discussed above with reference to claim 39, Applicants assert that Faltys 382 completely fails to teach or suggest “an implantable housing having therein electronics configured to output one or more stimulation signals...a first electrode assembly having first and second longitudinally extending contiguous regions... *wherein said housing and said first region are configured such that following implantation of said second region into the cochlea, said housing is rotatable about an axis of said housing... such that said second region implanted in the cochlea remains substantially stationary during said rotation*” as recited in part in claim 55. (Emphasis added.) As described in detail above with reference to claim 39, Faltys 382 requires that the implanted stimulator unit (ICS) remain in a fixed position while the electrode array is implanted in the cochlea due to the permanent attachment of the electrode array to the ICS. As such, Applicants assert that it would be unreasonable to assert that such a device

teaches or suggests a device as claimed in claim 55.

23. Applicants further assert that Faltys 101 or the other art of record, taken alone or in combination, fail to teach or suggest that which is missing from Faltys 382. Therefore, for at least these reasons, Applicants assert that new claim 55 is patentable over the art of record.

Claim 70

24. Applicants respectfully assert that Faltys 382 fails to teach or suggest all elements of Applicants' claim 70. Specifically, for the reasons discussed above with reference to claim 39, Applicants assert that Faltys 382 completely fails to teach or suggest "implanting an electrode assembly having first and second regions into the recipient such that said second region is at least partially implanted into a cochlea of the recipient... implanting a housing in said recipient, said housing having therein electronics configured to output one or more stimulation signals... ***repositioning said housing about an axis of said housing that is substantially aligned with a longitudinal axis of said first region such that said portion of second region implanted in the cochlea remains substantially stationary during said rotation***" as recited in part in claim 70. (Emphasis added.) As described in detail above with reference to claim 39, Faltys 382 requires that the implanted stimulator unit (ICS) remain in a fixed position while the electrode array is implanted in the cochlea due to the permanent attachment of the electrode array to the ICS. As such, Applicants assert that it would be unreasonable to assert that such a device teaches or suggests the method as claimed in claim 70.

25. Applicants further assert that Faltys 101 or the other art of record, taken alone or in combination, fail to teach or suggest that which is missing from Faltys 382. Therefore, for at least these reasons, Applicants assert that new claim 70 is patentable over the art of record.

Dependent Claims

26. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

27. In view of the foregoing, Applicants respectfully submit that this application is now in condition for allowance. A notice to his effect is respectfully requested.

28. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Thus, cancellations and amendments of above claims are not to be construed as an admission regarding the patentability of any claims.

Dated: November 13, 2007

Respectfully submitted,

Electronic signature: /Michael G. Verga/

Michael G. Verga

Registration No.: 39,410

CONNOLLY BOVE LODGE & HUTZ LLP

1875 Eye Street, NW

Suite 1100

Washington, DC 20006

(202) 331-7111

(202) 293-6229 (Fax)

Attorney for Applicant